UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,640	02/10/2004	Alexander B.H. Bakker	DX0763XB1	1877

28008 7590 08/29/2006

DNAX RESEARCH INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER	
O'HARA, EILEEN B	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,640	BAKKER ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to polypeptides, classified in class 530, subclass 350.

II. Claims 7-9, drawn to binding compounds comprising an antigen binding portion from an antibody which selectively binds polypeptide, classified in class 530, subclass 388.22, for example.

III. Claims 10-18, drawn to polynucleotides, vectors, host cells and a method for producing a polypeptide recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

IV. Claim 19, in so far as it is drawn to a method of contacting cell or tissue culture cells with an agonist of unknown composition, class and subclass unclassifiable.

V. Claim 19, in so far as it is drawn to a method of contacting cell or tissue culture cells with an antagonist of unknown composition, class and subclass unclassifiable.

VI. Claim 20, drawn to a method of screening for a compound which blocks interaction of a polypeptide with a receptor, comprising contacting said compound to said polypeptide in the presence of said receptor, classified in class 436, subclass 501, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of **Group I** and the polynucleotide of **Group III** the are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of **Groups I and III** together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of **Groups I and III** have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of **Group III** would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of **Group I**. As such, it would be burdensome to search the inventions of **Groups I and III**.

The polypeptide of **Group I** and the antibody of **Group II** are patentably distinct for the following reasons: while the inventions of both **Groups I and II** are polypeptides, in this instance, the polypeptide of **Group I** is a single chain molecule, whereas the polypeptide of **Group II** encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of **Group I** and the antibody of **Group II** are structurally distinct molecules; any relationship between a polypeptide of **Group I** and an antibody of **Group II** is dependent upon

the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptide of **Group I** is a large molecule which contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of **Group II** is defined in terms of its binding specificity to a small structure within **the disclosed SEQ ID NO**. Thus, immunization with the polypeptide of **Group I** would result in the production of antibodies outside the scope of **Group II**. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of **Group I** and **Group II** would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody which binds to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of **Group II**. Furthermore, antibodies which bind to an epitope of a polypeptide of **Group I** may be known even if a polypeptide of **Group I** is novel. In addition, the technical literature search for the polypeptide of **Group I** and the antibody of **Group II** is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of **Group III** and the antibody of **Group II** are patentably distinct for the following reasons: the antibody of **Group II** includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of **Group II** which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of **Group III** will not encode an antibody of **Group II**, and an antibody of **Group II** cannot be encoded by a polynucleotide of **Group III**. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of **Groups II** and **III** would impose a serious search burden since a search of the polynucleotide of **Group III** would not be used to determine the patentability of an antibody of **Group II** and vice-versa.

Inventions II and each of inventions IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the binding compounds can be used in a method of treating cells or tissue culture cells with an agonist or antagonist of inventions IV and V, or in a method of screening for a compound which blocks the interaction of a protein and its receptor, which are materially different methods.

Inventions I and VI are related as product and process of use. In the instant case the protein can be used in a method of screening for a compound which blocks interaction of the protein with its receptor, but the protein can also be used in a method of generating antibodies, which is a materially different method.

Invention I and each of inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein is not used in a method of treating cells or tissue culture cells with an agonist or antagonist.

Invention III and each of inventions IV, V and VI are unrelated. In the instant case the nucleic acid is not used in a method of treating cells or tissue culture cells with an agonist or

antagonist of the protein or in a method of screening for a compound which blocks interaction of the protein with its receptor.

The methods of inventions IV, V and VI are unrelated to each of the others. The starting materials, methods steps and goals of the inventions are different and are thus patently distinct.

Further Restriction Within Groups I-VI

3. For whatever group is elected, further restriction within the elected group is required, as follows: human DAP12, rodent DAP12, human DAP10, mouse DAP10, human MDL-1 or mouse MDL-1.

Although classifications for the nucleic acids, proteins, antibodies are overlapping, for instance 536/23.1, each represents a patentably distinct product, having different sequences and structures and requiring separate sequence searches. Therefore, the methods of using the nucleic acids, proteins and antibodies are also patentably distinct.

Applicants are advised that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Under Ochiai/Brouwer

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER